

# Timeline

Wednesday, August 1, 2018 9:45 AM

## Week of 18 June 18

- Brian dogged registrants about 90-days response submissions
- Monica Wait confirmed that TGA is fine for the 3 aquatic plant test studies
- Handoff from Brian to me
  - There is a lot of confusion about cost sharing between registrants

## Week of 25 June 18

- Viance claimed a repack exemption

## Week of 16 July 18

- I dug into the cost sharing situation

## Week of 23 July 18

- 7/26: Cost sharing alliances cemented (see Updated Tebuconazole Cost Sharing 26 Jul 18.xlsx)
  - Email came in from the ~~Tide~~ United Phosphorous Inc groups
  - There are now 2 group, the ~~Tide~~ United Phosphorous Inc and the Bayer
    - It is unclear to which ADAMA Ivitra belongs
      - ◻ ~~Perhaps they need an email~~
        - ◆ I figured it out; they are the same company as Viance
- Many registrants (the non-technical ones) are claiming a repack exemption. How do we grant that?
- 7/26: The ~~Tide~~ UPI alliance (Janelle Kay) submitted 3 study proposals and requested a meeting for the week of Aug 13
  - SS-1196; Chronic sediment – *Leptochirus*
  - SS-1197; Chronic sediment – *Hyalella*
  - SS-1197; Chronic sediment - *Chironomus*
  - ~~The studies will need to have MRIDs and be beaned~~
    - Done 8/9
  - The meeting is set for Aug 14 @ 11am (see meeting notes tab above)

## Week of 30 July 18

- 7/31: The Bayer alliance request and extension for three studies and to change for avian acute tox to dietary
  - The extensions are within the timeline, so we can grant them
  - Will I need to be an EFED for the study change request?
    - yes
- 7/31: I emailed Banza Djapao in ITRMD (?) about getting MRIDs for the proposals submitted by ~~Tide~~ UPI alliance
  - 7/31: He said he'd get back to me
  - 8/1: he helped me to assign MRIDs
    - ~~I will have to be an the protocols to EFED~~ done 8/9
- 7/31: email AD about granting repack exemptions and if that need a memo or what
  - ~~No response yet~~ (see email 6/8)
- 8/1: I emailed EFED and AD about the Bayer extension request and guideline change
  - ~~No response yet~~ (emails 3/8 and 6/8)
- 8/1: I emailed Monica Wait of EFED about the study proposals submitted by Tide et al
  - ~~No response yet~~ (email 3/8)

Week of 6 Aug 18

- 8/6:
  - On 2/8 Janelle Kay of the Tide UPI alliance asked if the EPA still requires submission of protocols for chronic adult honey bee or chronic larval provided the protocol follows OECD guidelines. ~~Will have to get back to her on that and then maybe tell the Bayer folks~~
    - See Nicole's email to Janelle Kay 6 Aug 18
  - On 3/8 Monica Wait of EFED informed me
    - that Amy Blankenship had been replaced by Michael Lowit on the EFED team;
    - that EFED has no objection to extending the deadlines, per the 8/1 Bayer request; and
    - that Michael Lowit would have to respond to the question of changing the dietary test with an acute test (RE Bayer ext request)
      - ~~No response yet~~
        - ◆ He pushed back on letting them change acute for dietary
  - On 3/8 Monica Wait also asked what date we would have in mind instead for the protocol review (see
    - ~~I will have to respond to her~~. I asked Nicole, and she said that she would get back to me
      - She said that the end of September (6 weeks, rather than the usual 8)
        - ◆ See notes from 7/26
    - Kevin sent me a confusing note related to this (6/8) and I haven't been able to pin him down on it; ~~will have to do that~~
      - He was confused
  - Dan Halper of AD responded that he would get back to me RE the repack exemptions
  - Michael Lowit emailed and wants to push back on changing the acute for the dietary study (see tide UPI request)
    - I conferred with Nicole and updated my draft of our response the extension request to include this pushback
- 8/7: Barry O'Keefe from EFED called trying to figure out what Janelle Kay wants to know about the DFR/TTF studies in the meeting on Aug 14th, since any information that could be needed is online. I sent Kay an email asking for details
  - ~~No response yet~~
    - 9/8: Kay responded (see email from today), sort of a punt. I emailed Barry to follow-up
      - ~~No response from Barry yet~~ (response on 13 aug)
      - ~~I will have to respond to Kay after Barry responds~~ (never responded directly to this--was moot)
- 8/8:
  - I have figured out, by reading the study protocols from J Kay, that the Tide UPI alliance is actually being led by United Phosphorous, and not Tide, However, they seem not to have submitted a 90-Days Response
    - ~~Find UP's 90-Days Response~~
      - Found in Brian Kettl's hard copy notes
  - I tried to upload the studies that Bonza got MIRDs for, but was unable to do so; Matt and Shanta suggested that this is ITRMD's responsibility. I emailed Bonza and asked for help
    - ~~No response yet~~
    - Bonza uploaded the documents
  - Spoke with Kevin, he thought that they were study results not protocols, so that's what that email was about
    - He suggested that we could ask EFED to get these reviewed at the end of Sept. so that the registrant would have a year to complete the studies
      - ~~Email Monica Wait and let her know the situation with the upload to documentum and the timeline~~
      - ~~Bean protocols to EFED~~
        - ◆ Done 8/9

- 8/9:
  - Nicole suggested that I could read up on bird toxicity (see email from today) and that would help us to decide the response to Bayer about switching from acute to dietary (see Bayer's extension request from 7/31)
    - ~~Research the stuff~~ done 8/10
  - Nicole also had suggestion for the response memo to the extension request (7/31)
    - ~~Review comments~~ done 8/10
- 8/10:
  - Accepted Nicole's comments on Bayer memo; current draft is Draft 3 nz jw nz jw
  - Did the research for about acute tox to passerines (see email 8/9)
  - Emailed Snyderman about how to associate the protocols submitted by U Phosphorous on behalf of the consortium with the other companies in the consortium
    - ~~No response yet~~
      - We will meet Monday to discuss
        - ◆ 8/13: he showed me how

Week of 13 Aug 18

- 8/13:
  - I heard from Tom Moriarty and Barry O'Keefe about the DFR/TTR question (see multiple emails)
    - Dug into the justification for the DFR/TTR requirements in the Scooping Doc and emailed the team and reviewed some REIs
    - I invited RD reps to the meeting--it seems that Bayer has satisfied the TFR but not UPI, so RD will be useful for knowing what is what and who can know what RE: data sand cost sharing
  - Kevin suggested that because of the **Ex. 5 Deliberative Process**
    - Set up a meeting with EFED for next week
      - Meeting set for 10 am 8/21
  - Dan suggested the repack exemptions were mine to coordinate with RD
    - Nicole said we can **Ex. 5 Deliberative Process**

**Ex. 5 Deliberative Process**

      - **Email Dan**
- 8/14:
  - Registrant meeting today with Tebuconazole Taskforce headed by UPI
    - See meeting notes
    - After meeting Barry O'Keefe wanted to clarify what he had told the reps about the number of study sites for DFR and TTR
      - ~~Call Barry with Nicole~~
        - ◆ He came by and we spoke in person (below)
      - **Email TF (Janelle Kay and Dave Olson)**
- 2/15:
  - Barry, Nicole, and I spoke regarding UPI's question of sites for the TTR study. UPI would like to submit data from fewer than 3 sites/crop (in this case, wheat and peanuts) and use EU data to satisfy the requirement
    - In the meeting, Barry sort of let on that we will accept anything and work with the registrant as best we can
    - After the meeting, Laura Bacon told Barry (I was not present) that it is best to ask for 3 sites/crop and get justification for anything less from the registrant
    - Later, Nicole spoke to Tom Moriarty (the branch chief in HED) on the phone and he said that what really matters is getting 3 sites total, not per crop
    - I don't know where this 3 is coming from. Janelle Kay seemed to know it as well. The

published guideline does not specify any numbers, just that a diversity of sites be sampled.

- **I will have to email Tom, Barry, Laura, and Nicole (CC) about this**
  - Nicole will forward answer to UPI as I will be on vacation on Monday
- Philip Ross of OGC got in touch. There have been petitions related to the 90-Days Responses and the GDCIs. He would like to see a bunch of documents (see email 2/15)
  - **Respond to Phillip**